

#### **IV. REMARKS / ARGUMENTS**

##### **A. Summary of Amendments**

The application still contains 47 claims.

Claims 16, 32 and 48 were previously cancelled without prejudice.

Independent claims 1, 17 and 33 have been amended to clarify the subject matter being claimed. Independent claims 49 and 50 have been cancelled and replaced with new claims 51 and 52 respectively.

Dependent claims 9, 10, 11, 25, 26, 27, 41, 42 and 43 have also been amended to clarify the subject matter being claimed.

Claims 2-8, 12-15, 18-24, 28-31, 34-40 and 44-47 are unchanged by the present amendment.

The Applicant believes that support for the amendments to the claims exists in the specification as originally filed and that no new matter has been added to the application by the present amendment.

## **B. Summary of Rejection and Reply**

The Applicant gratefully acknowledges the withdrawal of the Examiner's objection under 35 U.S.C. 132(a). The Applicant also gratefully acknowledges the withdrawal of the Examiner's rejection under 35 USC §102(e) of claims 1, 15, 17, 19, and 29-31 based on U.S. Patent No. 5,520,176 (hereinafter Cohen) and of the withdrawal of the Examiner's rejection under 35 USC §102(b) of claims 1, 3-5, 7-17, 18-20, 23-30, 32, 49 and 50 based on U.S. Patent No. 5,042,499 (hereinafter Frank et al.).

The Applicant has noted that, in the latest office action, the Examiner has rejected the claims currently pending based on new grounds. The Applicant has reviewed the Examiner's comments and arguments in detail and, in the present reply, has amended the claims to further clarify the invention for which protection is being sought.

The Applicant would like to thank Examiner Christopher A. Flory for taking the time to prepare a detailed Office Action.

***C. Claim Rejection under 35 USC §102(b)***

In the Office Action, the Examiner has rejected claims 1-15, 17-31, 33-47, 49 (now claim 51) and 50 (now claim 52) under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,442,940 (hereinafter Secker).

Independent claims 1, 17 and 33 have been amended and claims 49 and 50 have been cancelled and replaced with claims 51 and 52 respectively. The Applicant submits that the subject matter of claims 1-15, 17-31 and 33-47, as amended, and new claims 51-52 is both novel and non-obvious over Secker, as discussed below.

**Claims 1, 17, 33, 51 and 52**

The Examiner's attention is directed to the following highlighted features of independent claim 1 as amended:

1. A method for identifying heart rate feature events in a fetal heart rate signal, said method comprising:
  - a) receiving a fetal heart rate signal including a sequence of sample points, each sample point being indicative of a number of heart beats that occurred during a pre-determined time period;
  - b) identifying a plurality of distinct sections in said heart rate signal, wherein identifying the plurality of distinct sections includes:
    - i. **enclosing portions of said fetal heart rate signal in respective bounded areas to derive a set of segments, wherein:**
      - (a) each segment enclosed in a bounded area commences at a start sample point of said fetal heart rate signal and terminates at an end sample point of said fetal heart rate signal, the sample points between said start sample point and end sample point lying within said bounded area; and
      - (b) **each segment has a time duration determined based on at least one characteristic of the respective portion of said fetal heart rate signal;**
    - ii. **processing the set of segments derived to identify the plurality of distinct sections in said fetal heart rate signal;**
    - iii. associating sections in the plurality of distinct sections with respective labels, at least some of the labels conveying heart rate features;
  - c) releasing a signal indicative of said plurality of sections of said fetal heart rate signal.

The Applicant respectfully submits that the subject matter of amended independent claim 1 is neither anticipated nor rendered obvious by the prior art relied upon by the Examiner. Without limiting the generality of the foregoing, the Applicant submits that the above-emphasised features of claim 1 are neither taught nor suggested by Secker.

Secker describes an apparatus and associated process for evaluating the fetal condition and describes the processing of a fetal heart rate signal in order to identify acceleration and deceleration events. However, the manner in which Secker identifies accelerations and decelerations in a fetal heart rate signal differs significantly and substantially from the invention claimed in claim 1. The details of the mechanisms that Secker uses in order to identify accelerations and decelerations are described starting in column 23, line 8 through column 24, line 47. Generally speaking, the process described by Secker includes two stages.

A first stage, which is performed in the time domain, pertains to the pre-processing of the fetal heart rate signal. In this first stage, 'jumps' or outlying measurements and DC components of the fetal heart rate signal are removed. In addition, a window function is applied to the signal to remove spectral leakage prior to applying a Fast Fourier transform to the signal.

A second stage begins by converting the FHR signal to the frequency domain by the application of a Fast Fourier transform. Simply stated, while a time-domain graph shows how a signal changes over time, a frequency-domain graph shows how much of the signal lies within each given frequency band over a range of frequencies. In the frequency domain, the signal is processed in order to identify the frequency of the fetal heart rate variability as well as the amplitude of that variability. These two (2) elements, i.e. fetal heart rate variability and amplitude, are calculated in the frequency domain for time windows of about one (1) minute duration. Secker makes use of the information obtained in the frequency domain (frequency and amplitude variations) in order to classify accelerations and decelerations in the fetal heart rate signal.

In particular, Secker emphasises the superiority of processing the FHR signal in the frequency domain (see for example column 11, lines 17-28). This excerpt is reproduced below for the reader's convenience *[our emphasis]*:

*"According to the present invention, further processing is then performed in the frequency domain. For this purpose, preprocessing means are provided which include frequency transformation means, in particular Fast Fourier Transformation means, for transforming a fetal heart rate trace into the frequency domain. Despite the hard- and/or software required to perform frequency transformation, it has been found useful--in contrast to prior art approaches--to investigate the FHR trace also in the frequency domain, in order to obtain parameters reliably and completely describing the fetal heart rate."*

Secker then goes on in column 11, lines 45 to column 12, line 47 to indicate that "according to a further and most important feature the variability of the fetal heart rate is derived from this spectrum (i.e. the frequency spectrum). The inventor has found that the precision of the fetal heart rate variability calculation may be considerably increased if performed in the frequency domain [...]" In the above excerpts, Secker emphasises that the fetal heart rate assessment is better performed in the frequency domain and therefore teaches away from processing of the fetal heart rate in the time domain when identifying heart rate features.

In contrast, the present invention makes use of bounded areas to enclose portions of the heart rate signal in order to generate segments, wherein the time duration of a segment enclosed in a bounded area is based on at least one characteristic of the respective portion of said fetal heart rate signal. These segments are then processed in order to identify a plurality of distinct sections in the fetal heart rate signal. The sections are then associated with respective labels conveying heart rate features.

The Applicant submits that Secker fails to teach or suggest the invention claimed in claim 1 in a number of respects, in particular:

**Firstly, Secker does not teach or suggest identifying a plurality of distinct sections of a fetal heart rate signal by enclosing portions of the fetal heart rate signal in respective bounded areas to derive a set of segments.**

At page 3 of the Office Action, the Examiner relies on column 18, lines 37-49 to argue that Secker teaches processing the fetal heart rate signal to generate a set of segments each corresponding to a respective portion of the fetal heart rate signal enclosable in a bounded area.

The Applicant respectfully disagrees.

The excerpt relied upon by the Examiner does not teach or suggest enclosing portions of the fetal heart in bounded areas to derive a set of segments. Rather the excerpt relied upon by the Examiner merely describes the pre-processing of the fetal heart rate signals in order to remove ‘jumps’ or abnormal measurements from the fetal heart rate signals. As indicated in Secker (see column 18, line 39-40) such jumps may be caused, for example, by bad electrode contacts. Consequently these jumps are anomalies or errors in the fetal heart rate signals. Secker removes these jumps since they would otherwise impact the frequency spectrum obtained when applying a Fast Fourier Transform (FFT) to the fetal heart rate signal (see Secker column 18 line 54 to column 19 line 40 and Figure 5 step 45). Consequently, it is submitted that the processing described in Secker in the excerpt relied upon by the Examiner does not result in a set of segments but rather merely results in a fetal heart rate signal wherein the anomalies or “jumps” have been removed.

**Secondly, Secker does not teach or suggest [...] enclosing portions of the fetal heart rate signal in respective bounded areas to derive a set of segments, wherein each segment has a time duration determined based on at least one characteristic of the respective portion of the fetal heart rate signal.**

At page 3 of the Office Action, the Examiner relies on column 11, line 45 through column 12 lines 24) to argue that Secker teaches a bounded area of a segment having a length determined on a basis of at least one characteristic of the fetal heart rate signal.

The Applicant respectfully disagrees.

The excerpt relied upon by the examiner describes the manner in which the variability of the fetal heart rate signal is derived from the frequency spectrum of the signal. Secker makes use of this frequency spectrum to identify the variability of the fetal heart rate signal by identifying the spectral line with the highest amplitude in the associated spectrum.

At column 11, line 61 to column 12 line 1, Secker indicates that, in order to increase accuracy of the variability of the fetal heart rate signal derived, “it is possible to search only a limited region of the spectrum for the spectral line of maximum amplitude. This may e.g. be a predefined window in which variability is usually found. In a more sophisticated environment, the limits (and/or the width) of the spectral window are adaptive, i.e. once the true frequency of variability has been found, the window is automatically adjusted to the expected region. The limits, or the width, of the window may also be subject to expert editing.”

The Applicant would like to point out that the windows referred to by Secker in the above excerpt are windows in the frequency domain not windows in the time domain. Hence the “width” of the windows refers to a spectral width (i.e. a frequency range) and not to a time duration. Consequently, Secker suggests the use of spectral windows having adaptive width, this is completely unrelated to a time duration of a segment of a fetal heart rate signal.

Consequently, the above excerpt of Secker does not teach or suggest enclosing portions of the fetal heart rate signal in respective bounded areas to derive a set of segments, wherein each segment has a time duration determined based on at least one characteristic of the respective portion of the fetal heart rate signal.

The Applicant would also like to point out that it is unclear from the Office Action what the Examiner considers as corresponding to the “bounded area” and/or a segment. In the one hand, the Examiner refers to column 18, lines 37-49 of Seckers, which pertains to the pre-processing of a fetal heart rate signal to argue that the use of a bounded area is known. On the other hand, the Examiner refers to column 11, line 45 through column 12, line 24, which refers to the determination of the fetal heart rate variability which is performed using the frequency spectrum of the fetal heart rate signal, and points to the adaptive spectral windows as corresponding to the “bounded areas”. Should the Examiner maintain his rejection, the Applicant respectfully requests that the Examiner clarify what he considers as corresponding to a bounded area and a segment in Secker.

**Thirdly, Secker does not teach or suggest [...] enclosing portions of the fetal heart rate signal in respective bounded areas to derive a set of segments [...], and processing the set of segments derived to identify the plurality of distinct sections in the fetal heart rate signal.**

Since Secker does not teach or suggest enclosing portions of the fetal heart rate signal in respective bounded areas to derive a set of segments, it follows that Secker cannot teach or suggest “processing the set of segments derived to identify the plurality of distinct sections in the fetal heart rate signal.”

In light of the above, the applicant submits that the subject matter of claim 1 is neither taught nor suggested by Secker. Accordingly, the subject matter of claim 1 is believed to be both novel, non-obvious and in condition for allowance.

In addition, the Applicant submits that since claims 17, 33, 51 and 52 include language directed to similar features as the features emphasised above with reference to claim 1, the subject matter of claims 17, 33, 51 and 52 is also neither taught nor suggested by Secker.

Claims 2-15, 18-31 and 34-47

Claims 2-15, 18-31 and 34-47 depend directly or indirectly from one of independent claims 1, 17 and 33, and therefore incorporate all of the limitations recited in the respective independent claim, including those features already shown above to be absent from Secker relied upon by the Examiner. Accordingly, dependent claims 2-15, 18-31 and 34-47 are also believed to be novel and non-obvious over Secker.

***D. Claim Rejection under 35 USC §103(a)***

In the Office Action, the Examiner has rejected claims 1, 3-15, 17, 18-30, 33, 35-40, 45, 46, 49 (now 51) and 50 (now 52) under 35 USC §103(a) as being rendered obvious by U.S. Patent No. 5,042,499 (hereinafter Frank et al.) in view of Secker.

The Examiner has also rejected claims 2, 18, 34 and 41-44 under 35 USC §103(a) as being rendered obvious by Frank et al. in view of Secker in further view of U.S. Publication no. US 2003/006090A1 (hereinafter Jelliffe et al.).

The Applicant has amended the claims and submits that the subject matter of 1-15, 17-30, 33-46, as amended, and new claims 51-52 is both novel and non-obvious over Frank et al., considered alone or in combination with Secker and/or Secker and Jelliffe et al. as discussed below.

***Claims 1, 17, 33, 51 and 52***

The Examiner's attention is directed to the following highlighted features of independent claim 1 as amended:

1. A method for identifying heart rate feature events in a fetal heart rate signal, said method comprising:
  - a) receiving a fetal heart rate signal including a sequence of sample points, each sample point being indicative of a number of heart beats that occurred during a pre-determined time period;
  - b) identifying a plurality of distinct sections in said heart rate signal, wherein identifying the plurality of distinct sections includes:
    - i. **enclosing portions of said fetal heart rate signal in respective bounded areas to derive a set of segments, wherein:**
      - (a) each segment enclosed in a bounded area commences at a start sample point of said fetal heart rate signal and terminates at an end sample point of said fetal heart rate signal, the sample points between said start sample point and end sample point lying within said bounded area; and
      - (b) **each segment has a time duration determined based on at least one characteristic of the respective portion of said fetal heart rate signal;**
    - ii. **processing the set of segments derived to identify the plurality of distinct sections in said fetal heart rate signal;**
    - iii. associating sections in the plurality of distinct sections with respective labels, at least some of the labels conveying heart rate features;

- c) releasing a signal indicative of said plurality of sections of said fetal heart rate signal.

The Applicant respectfully submits that the subject matter of amended independent claim 1 is neither anticipated nor rendered obvious by the prior art relied upon by the Examiner. Without limiting the generality of the foregoing, the Applicant submits that the above-emphasised features of claim 1 are neither taught nor suggested by Frank et al. considered alone or in combination with Secker.

**Firstly, neither Frank et al. nor Secker teaches or suggests [...] enclosing portions of the fetal heart rate signal in respective bounded areas to derive a set of segments, wherein each segment has a time duration determined based on at least one characteristic of the respective portion of the fetal heart rate signal.**

In the Office action, at page 7, the Examiner acknowledges that Frank et al. does not expressly disclose that the length of a bounded area is determined on a basis of the fetal heart rate signal.

The Examiner however relies on Secker (column 11, line 45 to column 12 line 13) to show that it is known to enclose a portion of a heart rate signal in a bounded area to derive a segment, where the length of the bounded area is determined on a basis of at least one characteristic of the fetal heart rate signal.

The Applicant respectfully disagrees.

As argued above in connection with the rejection under 35 USC §102, the windows referred to by Secker in the above excerpt are windows in the frequency domain not windows in the time domain. Hence the “width” of the windows referred to by Secker in the above excerpt pertains to a spectral width (i.e. a range of frequencies) and not to a time duration. Consequently, Secker merely suggests the use of spectral windows having an adaptive width (adaptive frequency range), which is completely unrelated to a time duration of a segment of a fetal heart rate signal.

Consequently, the above excerpt of Secker does not teach or suggest enclosing portions of the fetal heart rate signal in respective bounded areas to derive a set of segments, wherein each

segment has a time duration determined based on at least one characteristic of the respective portion of the fetal heart rate signal.

**Secondly, neither Frank et al. nor Secker teaches or suggests [...] enclosing portions of the fetal heart rate signal in respective bounded areas to derive a set of segments, wherein each segment has a time duration [...], and processing the set of segments derived to identify the plurality of distinct sections in the fetal heart rate signal.**

Since neither Frank et al. nor Secker teaches or suggests enclosing portions of the fetal heart rate signal in respective bounded areas to derive a set of segments, it follows that Frank et al. and Secker cannot teach or suggest “processing the set of segments derived to identify the plurality of distinct sections in the fetal heart rate signal.”

In addition, the Applicant submits that Jelliffe et al. also neither teaches nor suggests the above-emphasised features of claim 1.

In light of the foregoing, the Applicant respectfully submits that the cited prior art references relied upon by the Examiner, whether taken alone or in combination, do not explicitly disclose or implicitly suggest all of the limitations of independent claim 1 as amended. Accordingly, the subject matter of claim 1 is believed to be both novel and non-obvious over the cited prior art and, as such, in condition for allowance.

In addition, the Applicant submits that, since claims 17, 33, 51 and 52 include language directed to similar features as the features emphasised above with reference to claim 1, the subject matter of claims 17, 33, 51 and 52 is also believed to be both novel and non-obvious over the cited prior art and, as such, in condition for allowance.

Comment

As an aside, and simply for purpose of clarity, the Applicant would like to reiterate the arguments submitted in the reply of September 5, 2007.

More specifically, the Applicant resubmits that Frank et al. does not teach or suggest identifying a plurality of distinct sections of a fetal heart rate signal by enclosing portions of the fetal heart rate signal in respective bounded areas to derive a set of segments.

At page 5 of the present Office Action, the Examiner contends that Frank et al. teaches “processing the heart rate signal to generate a set of segments” at col. 4, lines 24-31 and that each “segment being formed by enclosing a portion of said heart rate signal in a respective bounded area “ in Fig. 8 and at col. 6, lines 40-44. In particular, the Examiner argues that, for a digital signal, each digital data point of a measured heart rate signal (as disclosed in Frank et al.) is inherently based on a corresponding portion of heart rate signal and further is inherently enclosable in a bounded area (e.g. the sampling rate of the digital system determines a left and right time boundary for each data point collected).

The Applicant would like to point out that the “fetal heart rate signal” referred to in the claims is itself a signal comprised of a sequence of sample points. In particular, claim 1 includes “receiving a fetal heart rate signal including a sequence of sample points, each sample point being indicative of a number of heart beats that occurred during a pre-determined time period;”. Therefore, it is not clear to the Applicant what the Examiner considers in Frank et al. as corresponding to the fetal heart rate signal (including a sequence of sample points) and what he considers as corresponding to the set of segments referred to in the claims.

Consequently, should the Examiner maintain a rejection based on Frank et al., the applicant respectfully requests that the Examiner clarifies what he considers in Frank et al. as corresponding to the fetal heart rate signal (including a sequence of sample points) and what he considers as corresponding to the set of segments.

Claims 2-15, 18-31 and 34-47

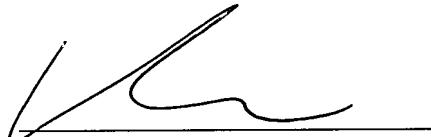
Claims 2-15, 18-31 and 34-47 depend directly or indirectly from one of independent claims 1, 17 and 33, and therefore incorporate all of the limitations recited in the respective independent claim, including those features already shown above to be absent from the references relied upon by the Examiner. Accordingly, dependent claims 2-15, 18-31 and 34-47 are also believed to be novel and non-obvious over the cited prior art and, as such, in condition for allowance.

### **V. CONCLUSION**

In view of the above, it is submitted that claims 1-15, 17-31, 33-47, 51 and 52 are in condition for allowance. Reconsideration of the rejections is requested. Allowance of claims 1-15, 17-31, 33-47 and 51 and 52 at an early date is solicited.

If the application is not considered to be in full condition for allowance, for any reason, the Applicant respectfully requests the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP 707.07(j) or in making constructive suggestions pursuant to MPEP 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Respectfully submitted,



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